

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Claims 1-35 (canceled)

36. (new) An aqueous pharmaceutical solution, which comprises: human parathyroid hormone (1-34) in a concentration of about 100-500 ug/ml; an acetate buffer to maintain the pH range of the solution from greater than 3 to 6; a stabilizing agent selected from the group consisting of glucose, trehalose, raffinose, sucrose, mannitol, sorbitol, inositol, glycerine, propylene glycol, and mixtures thereof; a parenterally acceptable preservative; and water; wherein said solution is sterile and ready for parenteral administration to a human patient.

37. (new) The pharmaceutical solution of claim 36 wherein the preservative is selected from m-cresol or benzyl alcohol.

38. (new) The pharmaceutical solution of claim 37 wherein the preservative is m-cresol at a concentration range of about 0.3 to about 1.0% by weight of the solution.

39. (new) The pharmaceutical solution of claim 36, 37, or 38, wherein the stabilizing agent is mannitol at a concentration of about 3% to 10% by weight of the total solution.

40. (new) The pharmaceutical solution of claim 36, 37, or 38 wherein the concentration of the buffer is in the range of about 2mM to 100mM.

41. (new) The pharmaceutical solution of claim 40 wherein the buffer includes acetic acid and sodium acetate.

42. (new) The pharmaceutical solution of claim 36, 37, 38, or 39, wherein said parathyroid hormone concentration is 250 ug/ml.

43. (new) An aqueous pharmaceutical solution, which comprises: 0.25 mg human parathyroid hormone (1-34), 50 mg mannitol, 2.5 mg m-cresol, 0.52 mg acetic acid and 0.12 mg sodium acetate mixed per 1 ml of water, wherein the solution is sterile and ready for parenteral administration to a human patient.

44. (new) A method for preparing a sterile, ready to administer pharmaceutical solution for parenteral administration comprising human parathyroid hormone (1-34), said method comprising the steps of:

a) admixing human parathyroid hormone (1-34) with: an acetate buffer to maintain a pH range from greater than 3 to less than 7; a stabilizing agent selected from the group consisting of glucose, trehalose, raffinose, sucrose, mannitol, sorbitol, inositol, glycerine, propylene glycol, and mixtures thereof; a parenterally acceptable preservative; and water wherein said parathyroid hormone is at a concentration of about 100-500 ug/ml; and

b) sterilizing the solution for parenteral administration without undergoing a step of freeze-drying or reconstitution prior to use by a patient.

45. (new) The method of claim 44, wherein the preservative is m-cresol in a range of about 0.3 to about 1.0% by weight of the solution; the stabilizing agent is about 3 to 10% by weight of the total solution; and the concentration of the buffer system is in the range of about 2mM to 100mM.

46. (new) The method of claim 45, wherein about 0.25 mg human parathyroid hormone (1-34), 50 mg mannitol, 2.5 mg m-cresol, 0.52 mg acetic acid and 0.12 mg sodium acetate are mixed per 1 ml of water.

47. (new) A sealed vial comprising:

a sterile, aqueous pharmaceutical solution ready for parenteral administration to a patient, said solution comprising human parathyroid hormone (1-34) in a concentration range from 100 ug/ml to 500 ug/ml; an acetate or tartrate buffer system to maintain the pH range of the solution from 3 to 6; a stabilizing agent selected from glucose, trehalose, raffinose, sucrose, mannitol, sorbitol, inositol, glycine and propylene glycol, or

mixtures thereof; a parenterally acceptable preservative; and water; wherein said solution has not been reconstituted in the vial from a powder.

48. (new) The sealed vial of claim 47 wherein the stabilizer is mannitol.

49. (new) The sealed vial of claim 48 wherein the parathyroid hormone (1-34) is at a concentration of 250 ug/ml, the mannitol is at a concentration of about 1% to about 20% by weight of the solution, and the preservative is at a concentration of about 0.1% to about 2% by weight of the solution.

50. (new) A sealed vial as in claim 49 wherein said preservative is selected from m-cresol or benzyl alcohol and the mannitol is at a concentration of about 3 to 10% by weight of the solution.